

REMARKS

Claims 1-6 are pending in the present Application. Claims 2-3 and 5-6 have been canceled, claims 1 and 4 have been amended, and claims 7-12 have been added, leaving Claims 1, 4 and 7-12 for consideration upon entry of the present Amendment.

Claims 1 and 4 have been amended to better define the invention. Support for these amendments can be found at least at page 5, lines 10-16; claim 2 as originally filed; page 6, lines 24-26; page 6, lines 8-14; and throughout the specification. Formula 1 of claims 1 and 4 has been amended to indicate that phytosphingosine molecules have a C18 backbone. Support for this amendment can be found at least at page 6, lines 8-14; and page 8, line 26-27. In addition, Applicants respectfully submit that one of ordinary skill in the art would recognize phytosphingosines as molecules having a C18 backbone. For instance, Crossman et al. (cited by the Examiner) states “Phytoshingosine are long chain bases that differ from sphingosine in that they have an additional hydroxyl at C-4 and have no double bond between carbon 4 and carbon 5” ... the configuration ... “to be D-ribo-1,3,4-trihydroxy-2-amniooctadecane.” (Crossman et al., page 1518, left column, lines 1-8; emphasis added) No new matter has been introduced by these amendments.

Reconsideration and allowance of the claims are respectfully requested in view of the above amendments and the following remarks.

New Claims

Claims 7-12 have been added to further claim the invention. Claims 7-12 are method claims corresponding to claims 1-6. Antecedent basis for claims 7-12 can be found at least at Experiments 1-2, and throughout the specification.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1-3 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification does not enable a person skilled in the art to make or use the invention commensurate in scope with the pending claims. (Office Action dated 4/15/2008, page 2) In particular, the Examiner stated while the specification is enabling for lung cancer, uterine cancer and breast cancer, the specification does not reasonably provide enablement for a wide

variety of cancers. (Office Action dated 4/15/2008, page 2) Applicants respectfully traverse this rejection.

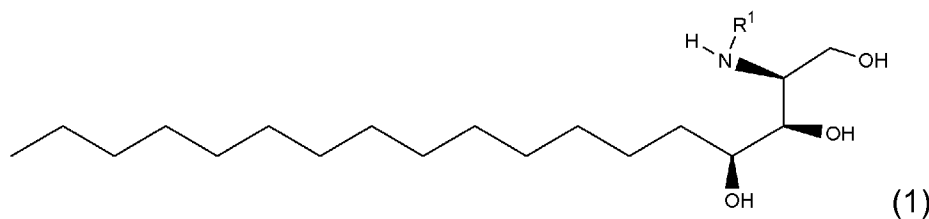
As currently amended, claim 1 is generally directed to a composition for cancer treatment, wherein the cancer is selected from the group consisting of lung cancer, uterine cancer, breast cancer and blood cell cancer. Applicants believe that amended claim 1 meets the requirements of 35 U.S.C. § 112, first paragraph. Applicants request a withdrawal of the rejection and allowance of the claims.

Claim Rejections Under 35 U.S.C. § 102(b)

Claims 1-2 and 4-5 stand rejected under 35 U.S.C. § 102(b), as allegedly anticipated by Jackson, *et al.*, (US 5,578,641)(hereinafter “Jackson”). (Office Action dated 4/14/2008, page 4) In making the rejection, the Examiner stated that Jackson teaches a composition comprising a compound (formula (9) at column 5, lines 19-25) which meets the limitations of claimed formula 1, wherein R¹ is ethanoyl or hydrogen (Office Action dated 4/14/2008, page 4). Applicants respectfully traverse this rejection.

To anticipate a claim, a reference must disclose each and every element of the claim. *Lewmar Marine v. Varient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987).

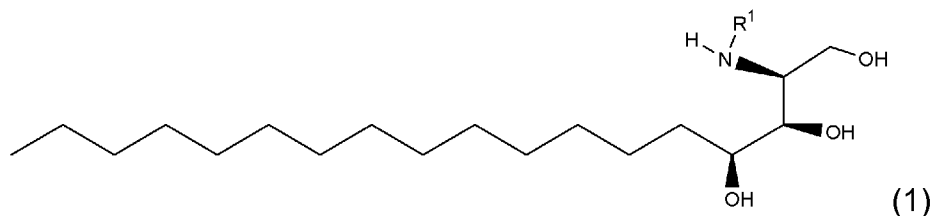
As currently amended, the claimed invention is generally directed to a composition for treatment of lung cancer, uterine cancer, breast cancer or blood cell cancer (claim 1); and a composition for the enhancement of radiosensitizing effect (claim 4) comprising a compound of formula (1):



wherein, R¹ is propanoyl group, butanoyl group, pentanoyl group, hexanoyl group, heptanoyl group, octanoyl group, nonanoyl group, decanoyl group, undecanoyl group, or dodecanoyl group.

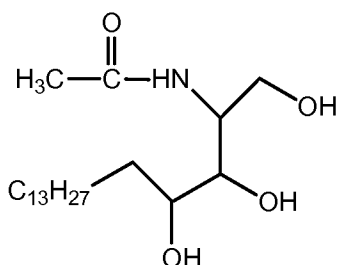
The claimed invention is further directed to a method of treating lung cancer, uterine cancer, breast cancer or blood cell cancer (claim 7); and a method of enhancing

radiosensitizing effect (claim 10) comprising administering to a human in need of treatment a therapeutically effecting amount of a compound of formula (1):

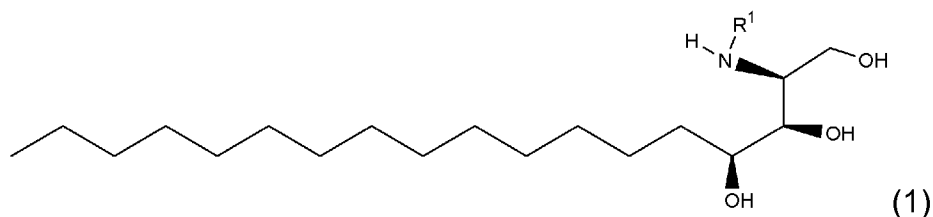


wherein, R¹ is propanoyl group, butanoyl group, pentanoyl group, hexanoyl group, heptanoyl group, octanoyl group, nonanoyl group, decanoyl group, undecanoyl group, or dodecanoyl group.

Jackson formula (9) has the following structure:



(formula (9) at column 5, lines 19-25). Thus, Jackson discloses a phytosphingosine of formula 1, wherein R¹ is ethanoyl or hydrogen. Jackson does not teach a compound of formula (1):



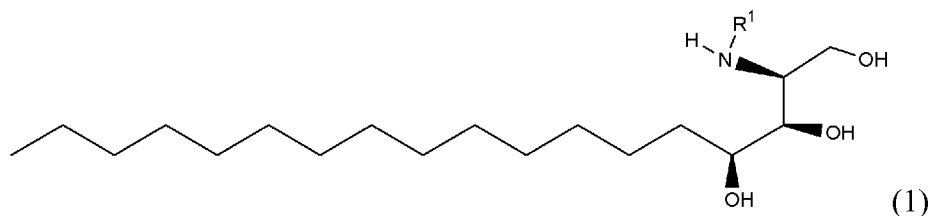
wherein, R¹ is propanoyl group, butanoyl group, pentanoyl group, hexanoyl group, heptanoyl group, octanoyl group, nonanoyl group, decanoyl group, undecanoyl group, or dodecanoyl group. For this reason at least, Jackson does not teach all elements of independent claims 1 and 4. Since Jackson does not teach all elements of the claimed invention, it cannot anticipate the claims under § 102(b). Claims 2 and 5 have been deleted. Applicants request a withdrawal of the rejection and allowance of the claims.

Claim Rejections Under 35 U.S.C. § 103(a)

Claims 1-6 stand rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over Jackson, for the reasons stated above, in view of Crossman, *et al.*, (J. Biol. Chem, Vol. 252 (16))(hereinafter “Crossman”). (Office Action dated 4/15/2008, page 6) Crossman is cited for teaching c18-phytoshinogsine to have NH₂, where R¹ is hydrogen. (Office Action dated 4/15/2008, page 6) Applicants respectfully traverse this rejection.

For an obviousness rejection to be proper, the Examiner must meet the burden of establishing that all elements of the invention are disclosed in the prior art; that the prior art relied upon, or knowledge generally available in the art at the time of the invention, must provide some suggestion or incentive that would have motivated the skilled artisan to modify a reference or combined references; and that the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). The obviousness inquiry also requires consideration of common knowledge and common sense. *KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742-43 (2007); *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006) (“Our suggestion test is in actuality quite flexible and not only permits, but requires, consideration of common knowledge and common sense.”)

As noted above, Jackson does not teach a compound of formula (1):



wherein, R¹ is propanoyl group, butanoyl group, pentanoyl group, hexanoyl group, heptanoyl group, octanoyl group, nonanoyl group, decanoyl group, undecanoyl group, or dodecanoyl group. Crossman simply discloses the structure of c18-phytoshinogsine. Neither Jackson, nor Crossman teach the compound of formula 1, having an R¹ group as recited in independent claims 1 and 4. For this reason at least, the combination of Jackson and Crossman does not teach all elements of independent claims 1 and 4. Since the combination of Jackson and Crossman does not teach all elements of the claimed invention, Applicants believe that a

prima facie case of obviousness under § 103(a) has not been made. Therefore, Applicants request a withdrawal of the rejection and allowance of the claims. Claims 2-3 and 5-6 have been deleted. Regarding newly added claims 7-12, neither Jackson, nor Crossman disclose the use of compound of formula 1 as a cancer agent or a radiosensitizing agent.

Conclusion

It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and allowance are requested.

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130.

Respectfully submitted,

CANTOR COLBURN LLP

By /Ian J.S. Lodovice/
Ian J. S. Lodovice
Registration No. 59,749

Date: July 14, 2008
CANTOR COLBURN LLP
20 Church Street, 22nd Floor
Hartford, CT 06130-3207
Telephone (860) 286-2929
Facsimile (860) 286-0115
Customer No.: 23413